

DEVICES FOR MODIFICATION OF AIRWAYS BY TRANSFER OF ENERGY

in part
5 This is a Continuation-in-part application of United States Application Serial No. 09/296,040 filed April 21, 1999, and of Continuation-in-part United States Application Serial No. 09/095,323 filed June 10, 1998 both of which applications are incorporated herein by reference in their entirety.

BACKGROUND OF THE INVENTION

Field of the Invention

10 The invention relates to a device for treating lung disease, and more particularly, the invention relates to a device for transferring energy into airway tissue such as that found in the airways of human lungs. This includes heating and applying RF energy to the airway. In the airways of the lung, the transfer of energy into the airway tissue stiffens that tissue or reduces the ability of the airways to constrict. In
15 in general the treatment reduces the resistance to the flow of air through the airway.

Brief Description of the Related Art

20 Asthma is a disease in which (i) bronchoconstriction, (ii) excessive mucus production, and (iii) inflammation and swelling of airways occur, causing widespread but variable airflow obstruction thereby making it difficult for the asthma sufferer to breathe. Asthma is a chronic disorder, primarily characterized by persistent airway inflammation. However, asthma is further characterized by acute episodes of additional airway narrowing via contraction of hyper-responsive airway smooth muscle.

25 Asthma stimuli may be allergenic or non-allergenic. Examples of allergenic stimuli include pollen, pet dander, dust mites, bacterial or viral infection, mold, dust, or airborne pollutants; non-allergenic stimuli include exercise or exposure to cold, dry air.

In asthma, chronic inflammatory processes in the airway play a central role. Many cells and cellular elements are involved in the inflammatory process, particularly mast cells, eosinophils T lymphocytes, neutrophils, epithelial cells, and even airway smooth muscle itself. The reactions of these cells result in an associated
5 increase in the existing sensitivity and hyperresponsiveness of the airway smooth muscle cells that line the airways to the particular stimuli involved.

The chronic nature of asthma can also lead to remodeling of the airway wall (i.e., structural changes such as thickening or edema) which can further affect the function of the airway wall and influence airway hyperresponsiveness. Other
10 physiologic changes associated with asthma include excess mucus production, and if the asthma is severe, mucus plugging, as well as ongoing epithelial denudation and repair. Epithelial denudation exposes the underlying tissue to substances that would not normally come in contact with them, further reinforcing the cycle of cellular damage and inflammatory response.

In susceptible individuals, asthma symptoms include recurrent episodes of shortness of breath (dyspnea), wheezing, chest tightness, and cough. Currently,
15 asthma is managed by a combination of stimulus avoidance and pharmacology.

Stimulus avoidance is accomplished via systematic identification and minimization of contact with each type of stimuli. It may, however, be impractical
20 and not always helpful to avoid all potential stimuli.

Asthma is managed pharmacologically by: (1) long term control through use of anti-inflammatories and long-acting bronchodilators and (2) short term management of acute exacerbations through use of short-acting bronchodilators. Both approaches require repeated and regular use of the prescribed drugs. High doses
25 of corticosteroid anti-inflammatory drugs can have serious side effects that require careful management. In addition, some patients are resistant to steroid treatment. Patient compliance with pharmacologic management and stimulus avoidance is often a barrier to successful asthma management.

Asthma is a serious disease with growing numbers of sufferers. Current management techniques are neither completely successful nor free from side effects.

Accordingly, it would be desirable to provide an asthma treatment which improves airflow without the need for patient compliance.

5 In addition to the airways of the lungs, other body conduits such as the esophagus, ureter, urethra, and coronary arteries, are also subject to periodic spasms that interfere with their normal function.

SUMMARY OF THE INVENTION

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The present invention relates to a device for treating airway tissue within the lungs by transfer of energy into the walls of the airway to reduce plugging of the airway, to prevent the airway from being able to constrict, to increase the inner airway diameter, or to reduce resistance to flow through the airway. The invention is particularly directed to the treatment of the airways in the lungs to reduce the effects of asthma and other lung disease. One variation of the invention includes the transfer of energy to the airway wall via the application of heat.

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The present invention provides devices to decrease airway responsiveness and airway resistance to flow which may augment or replace current management techniques. In accordance with one variation of the present invention, an energy transfer apparatus for treating conditions of the lungs by decreasing airway responsiveness includes transferring energy into an airway wall to alter the airway wall in such a manner that the responsiveness of the airway is reduced.

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In particular, the inventive device is an energy transfer apparatus which facilitates energy transfer with a mass of tissue within the airways of a lung. The inventive device is sized to enter the bronchus or bronchiole of a human lung to conduct energy transfer with the airway tissue therein. The inventive device may also

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be sized to fit within a bronchoscope. The bronchoscope may have a channel with a diameter of preferably 2 mm or less.

5 A variation of the inventive device includes a flexible elongated body having a proximal portion and a distal portion with a lumen extending between the proximal and distal portions. The flexible elongated body may be of sufficient stiffness to pass through a seal of a working channel of a bronchoscope and allow operation of the device through the working channel seal. The device may include an expandable portion that is adjacent to a distal portion of the elongated body. The expandable portion has a first state, e.g., a size, and a second state where the second state is
10 radially expanded in size from the elongated body. The device may include a temperature detecting element which is placed near to the expandable portion. The device also includes at least one energy transfer element at an exterior of the expandable portion, where the energy transfer elements are configured to contact the wall of the bronchus or bronchiole when the expanded portion is in an expanded state. The device may also include a deployment member that is configured to move the expandable portion between the first and second radially expanded states. The deployment member may extend between the expandable portion and the proximal portion of the elongated body. The inventive device may further include a distal tip located at a distal end of the apparatus. One variation of the inventive device
15 includes an expandable portion that has a diameter of less than 15 mm when in a second expanded state.

Another variation of the invention includes an expandable portion which includes pre-shaped tines. Such tines are configured to be in a first state within an elongated body and, when advanced out of the elongated body, to expand into a
25 second expanded state. The tines may be connected to each other with an expanding element to prevent the tines from entering multiple airways at a bifurcation.

Another variation of the invention includes an expandable portion comprised of a balloon. This variation of the invention may include the use of a fluid which

may expand the balloon into the second state. Yet another variation of this invention includes the use of a heat generating element in the balloon which conducts heat to the fluid to heat an exterior of the balloon. In this variation, the exterior of the balloon serves as the energy transfer element.

5 A further variation of the inventive device includes an expandable portion which comprises a plurality of legs which forms a basket. The legs of this variation may extend from a proximal joint that is found at an intersection of a distal portion of the elongated body to a distal joint that is adjacent to a distal tip. Each leg may have a center that is substantially parallel to the elongated body so that there is sufficient
10 contact between the airway walls and the parallel portion of the leg. The center that is substantially parallel is usually referred to as the active region of the leg. The

The legs of this variation may be spaced around a circumference of the elongated body to form a basket. The legs of this variation may have a circular cross section or a rectangular cross section, or other non-axisymmetric cross sections. The
15 cross sections may be chosen to allow ready deployment from a first state to a second expanded state, while resisting out-of-plane bending which may distort the spacing of the legs or the contact of electrodes with the airway surface. One variation of the invention includes a basket in which the distance between the proximal and distal joint is less than 35 mm when the basket is not expanded. Another variation of this
20 invention includes a basket that comprises four or five legs. In this case, the legs may be placed evenly around a circumference of the elongated body. In this case the legs may be found at intervals of 90 or 72 degrees. Other variations of the invention include devices having less than four legs or more than five legs. Another variation of this inventive device includes placing a temperature detecting element on one or
25 on more legs. In this variation, the temperature of one leg may be monitored or the temperature of several legs may be independently monitored to control the energy delivery. In a further variation, multiple temperature sensing elements may be combined with independent control of energy to each leg. Both of these variations

may also apply to a variation of the device having pre-shaped tines. The legs may be soldered or made to adhere using adhesives to the elongated body at the proximal and distal ends. Another variation of the invention includes a multi-lumen elongated body into which a portion of each leg is inserted. It is also contemplated that an elongated member may be reinforced via a reinforcing member. Such a reinforcing member may include a coiled or braided wire, polymeric insert, or any other similar reinforcing member .

The energy transfer element of the invention may include an element that directly heats tissue by delivering current such as an RF based electrode. The RF electrode may be either bipolar or monopolar or a heated element that conductively heats tissue. In variations of the invention using RF energy, the frequency of the RF may be selected to be in the 400 kHz range or any other standard medical range used in electro-surgical applications.

When the electrode directly heats the tissue, the heated element may use AC or DC current to resistively heat the element. RF energy may also be used to resistively heat the element. An indirect method of heating includes a resistively heated element that conducts heat to the expandable portion or directly to the airway. The invention may also include a combination of the types of electrodes mentioned above.

In the variation of the invention in which the expandable portion comprises a basket, each of the energy transfer elements may be a RF electrode that is attached to each leg. The electrode may be fastened by a heat shrink fastener. In such a case, a temperature detecting element may be placed on the leg and underneath the fastener. A resistance heating element may be coiled around a portion of the leg. In this case, a temperature detecting element may be placed underneath the coil. Other examples of the energy transfer element include a polymeric heating element, an electrically conductive paint, or a printed flex circuit which are on a portion of the leg. Another variation employs the basket leg itself as either a RF electrode or a heated element.

In such cases, the temperature sensing element may be attached directly to a basket leg by soldering, welding, adhesive bonding, or other means.

Another variation of the invention includes a sheath slidably coupled to and exterior to the expandable portion. The expandable portion may be resilient and self-expand into the second state when no longer confined by the sheath. For example, the sheath may be withdrawn in a proximal direction or the expandable portion may be advanced out of the sheath.

Yet another variation of the invention includes a deployment member comprising a handle adjacent to a proximal end of the elongated body. The elongated body may be slidably attached to the handle. The deployment member may also comprise a wire that extends from the handle through the lumen of the elongated body and is fixedly attached to the distal tip. This wire may also provide a current to the energy transfer members. The elongated body, the wire, and the distal tip may be slidably moveable in a distal and proximal direction. This variation of the deployment member may also include a stop configured to prevent distal movement of the wire beyond a deployment point. In this variation, beyond the deployment point, movement of the elongated body against the non-moving distal tip causes the expansion member to expand from a first state into a second expanded state.

Another variation of the invention includes a deployment member comprising a sheath that covers the elongated member and expandable portion and a handle at a proximal end of the sheath. The sheath may be slidably attached to the handle while the elongated member is rigidly attached to the handle. A wire may extend from said handle to a distal tip through a lumen of the elongated member. The variation may include a first control member attached to the sheath and slidably attached to the handle where proximal movement of the first control member causes the sheath to retract on the elongated member and uncover the expandable portion. This variation may also include a second control member which is attached to the wire where proximal movement of the second control member causes the distal tip and the

expandable portion to retract against the non-moving elongated member and causes the expandable portion to radially expand into a second state.

Another variation of the invention includes a deployment member having force compensation or deflection limiting stops to prevent over-expansion of the expandable member when deployed within the body.

A variation of the invention includes placing a sheath exterior to the elongated body and expandable portion such that the expandable portion is placed within the sheath in a first unexpanded state. When the expandable portion is no longer restrained by the sheath, the expandable portion expands into its second state. The invention may also include a control member moveably secured to the handle where the member is configured to advance the elongated body and the wire in the distal and proximal directions. Another variation of the invention includes a detent means for maintaining the elongated body distally of the deployment point. The control member may also be configured to frictionally maintain the elongated body distally of the deployment point. In these cases, the expandable portion will be in the second expanded state. Other variations of the inventive device may include use of levers, control wheels, or screw mechanisms in place of a control member.

Another variation of the inventive device includes a distal tip that may be configured to prevent gouging of the airway tissue. The distal tip may have a redundant joint to prevent separation of the tip from the apparatus. The distal tip may also be sized to fit within a bronchoscope.

Another variation of the invention includes a central wire extending from the distal tip to the proximal portion of the device. The wire may be configured to provide a current to the energy transfer elements. A temperature detecting element may also be attached to the wire.

The inventive device may also be radiopaque or may have radiopaque elements.

Another variation of the invention includes providing a steering member in the device to deflect the distal tip of the apparatus in a desired direction.

Another variation of the invention includes placing a vision system on the apparatus. The vision system may include a fiber-optic cable or a CCD chip.

5 Another variation of the invention includes providing a power supply configured to deliver energy through the energy transfer elements to the airway walls. The power supply may be configured to include a high temperature shut off or one which shuts down if a minimum temperature is not detected within a predetermined time or if a minimum temperature slope is not detected during a predetermined time.

10 The invention further includes a kit comprising an energy transfer apparatus for facilitating energy transfer into a mass of airway tissue and a generator configured to delivery energy to the energy transfer apparatus. The kit may further include a bronchoscope.

15 The invention further includes an energy transfer apparatus for facilitating energy transfer into a mass of airway tissue within a lung, the energy transfer apparatus having been rendered sterile for the purposes of prevention of infection of the lung.

20 The invention further include s a modified lung configured to have an artificially altered airway within the lung, the airway being artificially altered by transfer of energy to the airway such that the airway has a reduced ability to constrict, an increased airway diameter, a increase in resistance to plugging, and a decrease in resistance to airflow.

25 The present invention may be used for a treatment of asthma or other constriction or spasm of a bodily conduit by application of energy. The treatment reduces the ability or propensity of the airway to contract, reduces plugging of the airway, increases the inner airway diameter, and/or reduces resistance to flow through the airway.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in greater detail with reference to the various embodiments illustrated in the accompanying drawings:

5 FIG. 1 is a cross sectional view of a medium sized bronchus in a healthy patient.

FIG. 2 is a cross sectional view of a bronchiole in a healthy patient.

FIG. 3 is a cross sectional view of the bronchus of FIG. 1 showing the remodeling and constriction occurring in an asthma patient.

10 FIG. 4 is an illustration of the lungs being treated with a device according to the present invention.

FIG. 5A is a partial side view of a variation of the inventive device having a plurality of wire shaped electrodes.

15 FIG. 5B is a cross sectional side view of another variation of a device having a plurality of wire shaped electrodes with a deployment wire attached to a distal tip of the device.

FIG. 5C shows a partial view of a variation of an elongated member of inventive device having a plurality of lumens for nesting the legs of the basket.

20 FIGS. 5D-5I illustrate a variation of the invention and a deployment member for deploying the device.

FIGS. 5J-5L illustrate examples of energy transfer elements of the device.

FIG. 5M shows a partial view of a thermocouple attached to a basket leg.

FIGS. 6A-6D illustrates distal joints of the invention.

FIG 6E illustrates a proximal joint of the invention.

25 FIGS. 7A-7D illustrates a series and parallel wiring of legs of the basket.

FIGS. 8A-8C illustrate examples of variable thicknesses of legs of the basket.

FIGS. 9A-9D illustrate examples of a basket formed from a single sheet or piece of material.

FIG. 10 is a side cross sectional view of a variation of the inventive device having a balloon with electrodes positioned exterior to the balloon.

FIG. 11 is a partial side view of a variation of the inventive device having a balloon with heat generating elements positioned within the balloon for indirect heating of the tissue.

FIG. 12 is cross sectional view of the inventive device with electrodes and pre-shaped tines as the expandable member.

FIG. 13 is a cross sectional view of a variation of the inventive device with energy transfer elements positioned on expandable balloons.

FIG. 14 is an illustration of a variation of the inventive device with electrodes positioned in grooves.

FIG. 15 is an illustration of a variation of the inventive device with electrodes and a biasing element.

FIG. 16 is an illustration of another variation of the inventive device having electrodes and a biasing element.

FIG. 17 is a partial side view of a variation of the inventive device having electrodes exposed by cut away sections of an elongated member.

FIG. 18 is a partial side view of the inventive device with electrodes positioned on a loop shaped member.

FIG. 19 is a cross sectional view of a variation of the inventive device having a looped shaped electrode in an unexpanded position.

FIG. 20 is a cross sectional view of the variation of FIG. 19 with the looped shape electrode in an expanded position.

DETAILED DESCRIPTION

Reducing the Ability of the Airway to Contract

5 The inventive airway energy treatment may be used to reduce the ability of the airways to narrow or to reduce in diameter due to airway smooth muscle contraction. This treatment to reduce the ability of the smooth muscle to contract lessens the severity of an asthma attack. The reduction in the ability of smooth muscle to contract may be achieved by treating the smooth muscle itself or by treating other tissues which in turn influence smooth muscle contraction or the response of the airway to smooth muscle contraction. Treatment may also reduce
10 airway responsiveness or the tendency of the airway to narrow or to constrict in response to a stimulus.

The amount of smooth muscle surrounding the airway can be reduced by exposing the smooth muscle to energy which either kills the muscle cells or prevents these cells from replicating. The reduction in smooth muscle reduces the ability of
15 the smooth muscle to contract and to narrow the airway during a spasm. The reduction in smooth muscle and surrounding tissue has the added potential benefit of increasing the caliber or diameter of the airways, reducing the resistance to airflow through the airways. In addition to use in debulking smooth muscle tissue to open up the airways, the device of the present invention may also be used for eliminating the
20 smooth muscle altogether by thermally damaging or destroying it. The elimination of the smooth muscle prevents the hyper-reactive airways of an asthma patient from contracting or spasming, reducing or eliminating this asthma symptom.

The ability of the airway to contract can also be altered by treatment of the smooth muscle in particular patterns. The smooth muscle is arranged around the
25 airways in a generally helical pattern with pitch angles ranging from about -30 to about +30 degrees. Thus, the treatment of the smooth muscle by energy which is selectively delivered in an appropriate pattern interrupts or cuts through the helical pattern at a proper pitch and prevents the airway from constricting. This procedure of

patterned application of energy eliminates contraction of the airways without completely eradicating smooth muscle and other airway tissue. A pattern for treatment may be chosen from a variety of patterns including longitudinal or axial stripes, circumferential bands, helical stripes, and the like as well as spot patterns having rectangular, elliptical, circular or other shapes. The size, number, and spacing of the treatment bands, stripes, or spots are chosen to provide a desired clinical effect of reduced airway responsiveness while limiting insult to the airway to a clinically acceptable level.

The patterned treatment of the tissues surrounding the airways with energy provides various advantages. The careful selection of the portion of the airway to be treated allows desired results to be achieved while reducing the total healing load. Patterned treatment can also achieve desired results with decreased morbidity, preservation of epithelium, and preservation of a continuous or near continuous ciliated inner surface of the airway for mucociliary clearance. The pattern of treatment may also be chosen to achieve desired results while limiting total treatment area and/or the number of airways treated, thereby improving speed and ease of treatment.

Application of energy to the tissue surrounding the airways also may be used to cause the DNA of the cells to become cross linked. The treated cells with cross linked DNA are incapable of replicating. Accordingly, over time, as the smooth muscle cells die, the total thickness of smooth muscle decreases because of the inability of the cells to replicate. The programmed cell death causing a reduction in the volume of tissue is called apoptosis. This treatment does not cause an immediate effect but causes shrinking of the smooth muscle and opening of the airway over time and substantially prevents re-growth. The application of energy to the walls of the airway may also be used to cause a cross linking of the DNA of the mucus gland cells thereby preventing them from replicating and reducing excess mucus plugging or production over time.

5 The ability of the airways to contract may also be reduced by altering mechanical properties of the airway wall, such as by increasing stiffness of the wall or by increasing parenchymal tethering of the airway wall. Both of these methods increase the strength of the airway wall and opposes contraction and narrowing of the airway.

10 There are several ways to increase the stiffness of the airway wall. One way to increase stiffness is to induce fibrosis or wound healing response by causing trauma to the airway wall. The trauma can be caused by delivery of therapeutic energy to the tissue in the airway wall or by mechanical insult to the tissue. The energy is preferably delivered in such a way that it minimizes or limits the intra-luminal thickening that can occur.

15 Another way to increase the effective stiffness of the airway wall is by altering the submucosal folding of the airway upon narrowing. The submucosal layer is directly beneath the epithelium and its basement membrane and inside the airway smooth muscle. As an airway narrows, its perimeter remains relatively constant, with the mucosal layer folding upon itself. As the airway narrows further, the mucosal folds mechanically interfere with each other, effectively stiffening the airway. In asthmatic patients, the number of folds is fewer and the size of the folds is larger, and thus, the airway is free to narrow with less mechanical interference of mucosal folds than in a healthy patient. Thus, asthmatic patients have a decrease in airway stiffness and the airways have less resistance to narrowing.

20 The mucosal folding in asthmatic patients can be improved by treatment of the airway in a manner which encourages folding. Preferably, a treatment will increase the number of folds and/or decrease the size of the folds in the mucosal layer. For example, treatment of the airway wall in a pattern such as longitudinal stripes can encourage greater number of smaller mucosal folds and increase airway stiffness.

5 The mucosal folding can also be increased by encouraging a greater number of smaller folds by reducing the thickness of the submucosal layer. The decreased thickness of the submucosal layer may be achieved by application of energy which either reduces the number of cells in the submucosal layer or which prevents replication of the cells in the submucosal layer. A thinner submucosal layer will have an increased tendency to fold and increased mechanical stiffening caused by the folds.

10 Another way to reduce the ability of the airways to contract is to improve parenchymal tethering. The parenchyma surrounds airways and includes the alveolus and tissue connected to and surrounding the outer portion of the airway wall. The parenchyma includes the alveolus and tissue connected to and surrounding the cartilage that supports the larger airways. In a healthy patient, the parenchyma provides a tissue network which connects to and helps to support the airway. Edema or accumulation of fluid in lung tissue in asthmatic patients is believed to decouple the airway from the parenchyma reducing the restraining force of the parenchyma which opposes airway constriction. Application of therapeutic energy can be used to treat the parenchyma to reduce edema and/or improve parenchymal tethering.

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20 In addition, the applied energy may be used to improve connection between the airway smooth muscle and submucosal layer to the surrounding cartilage, and to encourage wound healing, collagen deposition, and/or fibrosis in the tissue surrounding the airway to help support the airway and prevent airway contraction.

Increasing the Airway Diameter

25 Airway diameter in asthmatic patients is reduced due to hypertrophy of the smooth muscle, chronic inflammation of the airway tissues, and general thickening of all parts of the airway wall. The overall airway diameter can be increased by a variety of techniques to improve the passage of air through the airways. Application of energy to the airway smooth muscle of an asthmatic patient can be used to debulk

or reduce the volume of smooth muscle. This reduced volume of smooth muscle increases the airway diameter for improved air exchange.

5 The airway diameter can also be increased by reducing inflammation and edema of the tissue surrounding the airway. Inflammation and edema (accumulation of fluid) of the airway occur in an asthmatic patient due to irritation. The inflammation and edema can be reduced by application of energy to stimulate wound healing and regenerate normal tissue. Healing of the epithelium or sections of the epithelium experiencing ongoing denudation and renewal allows regeneration of healthy epithelium with less associated airway inflammation. The less inflamed
10 airway has an increased airway diameter both at a resting state and in constriction. The wound healing can also deposit collagen which improves parenchymal tethering.

Inflammatory mediators released by tissue in the airway wall may serve as a stimulus for airway smooth muscle contraction. Smooth muscle contraction, inflammation, and edema can be reduced by a therapy which reduces the production and release of inflammatory mediators. Examples of inflammatory mediators are
15 cytokines, chemokines, and histamine. The tissues which produce and release inflammatory mediators include airway smooth muscle, epithelium, and mast cells. Treatment of these structures with energy can reduce the ability of the airway structures to produce or release inflammatory mediators. The reduction in released
20 inflammatory mediators will reduce chronic inflammation, thereby increasing the airway inner diameter, and may also reduce hyper-responsiveness of the airway smooth muscle.

A further process for increasing the airway diameter is by denervation. A resting tone of smooth muscle is nerve regulated by release of catecholamines. Thus,
25 by damaging or eliminating nerve tissue in the airways the resting tone of the smooth muscle will be reduced, and the airway diameter will be increased.

Reducing Plugging of the Airway

Excess mucus production and mucus plugging are common problems during both acute asthma exacerbation and in chronic asthma management. Excess mucus in the airways increases the resistance to airflow through the airways by physically blocking all or part of the airway. Excess mucus may also contribute to increased numbers of leukocytes found in airways of asthmatic patients by trapping leukocytes. Thus, excess mucus can increase chronic inflammation of the airways.

One type of asthma therapy involves treatment of the airways with energy to target and reduce the amount mucus producing cells and glands and to reduce the effectiveness of the remaining mucus producing cells and glands. The treatment can eliminate all or a portion of the mucus producing cells and glands, can prevent the cells from replicating or can inhibit their ability to secrete mucus. This treatment will have both chronic benefits in increasing airflow through the airways and will lessen the severity of acute exacerbations.

Illustrated below are different treatment devices for transferring energy into the airways. Described below are just some of the examples of the type of treatment devices which may be used to treat airway tissue according to the present invention. It should be recognized that each of the treatment devices described below can be modified to deliver or to remove energy in different patterns depending on the treatment to be performed. The treatment devices may be actuated continuously for a predetermined period while stationary, may be pulsed, may be actuated multiple times as they are moved along an airway, may be operated continuously while moving the device in an airway to achieve a "painting" of the airway, or may be actuated in a combination of any of these techniques. The particular energy application pattern desired can be achieved by configuring the treatment device itself or by moving the treatment device to different desired treatment locations in the airway.

5 The treatment of an airway with the treatment device may involve placing a
visualization system such as an endoscope or bronchoscope into the airways. The
treatment device is then inserted through or next to the bronchoscope or endoscope
while visualizing the airways. Alternatively, the visualization system may be built
directly into the treatment device using fiber optic imaging and lenses or a CCD and
lens arranged at the distal portion of the treatment device. The treatment device may
also be positioned using radiographic visualization such as fluoroscopy or other
external visualization means. The treatment device which has been positioned with a
distal end within an airway to be treated is energized so that energy is applied to the
10 tissue of the airway walls in a desired pattern and intensity. The distal end of the
treatment device may be moved through the airway in a uniform painting like motion
to expose the entire length of an airway to be treated to the energy. The treatment
device may be passed axially along the airway one or more times to achieve adequate
treatment. The "painting-like" motion used to exposed the entire length of an airway
15 to the energy may be performed by moving the entire treatment device from the
proximal end either manually or by motor. Alternatively, segments, stripes, rings or
other treatment patterns may be used.

20 According to one variation of the invention, the energy is transferred to or
from an airway wall in the opening region of the airway, preferably within a length of
approximately two times the airway diameter or less, and to wall regions of airways
distal to bifurcations and side branches, preferably within a distance of approximately
twice the airway diameter or less. The invention may also be used to treat long
segments of un-bifurcated airway.

25 Decreasing Resistance to Airflow

There are several ways to decrease the resistance to airflow though the
airways which occurs in asthma patients both at rest and during an asthma attack.
One such treatment alters the structure of the airway, such as by reducing the amount

of airway tissue. For example, the addition of energy to the airway tissue may cause the DNA of the muscle cells to become cross linked. The smooth muscle cells with cross linked DNA cannot replicate. Thus, over time, as smooth muscle cells die, the total thickness of the muscle decreases because of the inability of the cells to replicate. Another treatment alters the function of the airway, such as by reducing smooth muscle contraction, mucus gland secretions, or disrupting the inflammatory response. These treatments can be performed by applying energy of different types and in different patterns to achieve the desired results. In such cases, stiffness of the airway is increased as the energy induces a fibrosis or wound healing response that causes trauma to the airway wall.

FIGS. 1 and 2 illustrate cross sections of two different airways in a healthy patient. The airway of FIG. 1 is a medium sized bronchus having an airway diameter D1 of about 3 mm. FIG. 2 shows a section through a bronchiole having an airway diameter D2 of about 1.5 mm. Each airway includes a folded inner surface or epithelium 10 surrounded by stroma 12 and smooth muscle tissue 14. The larger airways including the bronchus shown in FIG. 1 also have mucous glands 16 and cartilage 18 surrounding the smooth muscle tissue 14. Nerve fibers 20 and blood vessels 22 also surround the airway.

FIG. 3 illustrates the bronchus of FIG. 1 in which the smooth muscle 14 has hypertrophied and increased in thickness causing the airway diameter to be reduced from the diameter D1 to a diameter D3.

FIG. 4 is a schematic side view of the lungs being treated with an energy transferring apparatus 30 according to the present invention. The device 30 is an elongated member for facilitating exchanging energy with a mass of airway tissue at a treatment site 34 within the lungs. The device 30 must be of a size to access the bronchus or bronchioles of the human lung. The device may be sized to fit within bronchoscopes, preferably, with bronchoscopes having a working channel of 2 mm or

less. Also, the device should be of sufficient stiffness to fit and operate through the seal covering the working channel a bronchoscope.

The energy may be delivered by the treatment device 30 in a variety of treatment patterns to achieve a desired response. Examples of patterns are discussed in further detail below. The energy which is delivered by the treatment device 30 may be any of a variety of types of energy including, but not limited to, radiant, laser, radio frequency, microwave, heat energy, or mechanical energy (such as in the form of cutting or mechanical dilation).

Also, the device may, but is not necessarily, configured to deliver energy in non-intersecting strip patterns which are parallel with a central axis of an airway. For example, other variations of the device may be configured to deliver energy in a torsional pattern, or in a circumferential pattern around a wall of the airway. Such configurations which may be determined to deliver energy to the airway tissue that maximize the ability of the airway to permit airflow are considered to be within the scope of this invention.

The inventive devices include tissue contacting electrodes configured to be placed within the airway. These devices can be used for delivering radio frequency in either a monopolar or a bipolar manner or for delivering other energy to the tissue, such as conducted heat energy from resistively heated elements. As shown in FIG. 4, for monopolar energy delivery, one or more electrodes of the treatment device are connected to a single pole of the energy source 32 and an optional external electrode 44 is connected to an opposite pole of the energy source. For bipolar energy delivery, multiple electrodes are connected to opposite poles of the energy source 32 and the external electrode 44 is omitted. Naturally, the external electrode 44 depicted in FIG. 4, is not required in the case of bipolar energy delivery. The number and arrangement of the electrodes may vary depending on the pattern of energy delivery desired. The treatment devices of FIGS. 5A-10, and 12-20 are used to deliver radiant or heat energy to the airway. The treatment device of FIG. 11 may also be used to

deliver indirect radio frequency, microwave energy, or conductive heat energy to the tissue. In cases of heat energy generated by resistive heating, the current may be AC or DC current or in the case of AC, the current may be delivered in the RF range. The use of RF provides an added safety feature of minimizing the possibility of harm to the patient caused by escaped current. The device may also use a combination of any of the energy transferring element configurations described herein.

The following illustrations are examples of the invention described herein. It is contemplated that combinations of aspects of specific embodiments or combinations of the specific embodiments themselves are within the scope of this disclosure.

The treatment device 302 of FIG. 5A includes an elongated member 102 for delivering an expandable member 104 to a treatment site. The expandable member 104 may have a plurality of energy transfer elements (not illustrated) which are placed on a plurality of basket legs 106 to transfer energy at the treatment site. In this variation, the expandable member comprises a basket 104 which is defined by a number of basket legs 106. The basket legs 106 are formed from a plurality of elements which are soldered or otherwise connected together at two connection areas, a proximal joint 108 and a distal joint 110.

A desirable length of the basket 104, or the expandable portion of any variation of the invention, depends upon numerous factors. One consideration in determining a desired length of the expandable member, e.g., the distance between the joints of the basket, of the inventive device is related to the dimension of the target area or treatment region. For instance, some other factors include considerations of minimizing the amount of the expandable portion which is distal to the treatment region for optimized access, minimizing the amount of the expandable portion that is proximal to the treatment region for visualization and access concerns, and setting a desirable length of the expandable portion that will contact a sufficient portion of the treatment region during each application of the device. A compromise

of such factors along with other considerations provides a desirable length for the expandable portion of the device. Preferably, the distance between the distal and proximal joints of the basket is less than 35 mm when the basket is in a first unexpanded state.

5 The legs 106 may be selected from a material that allows the basket to expand without plastic deformation. For example, the legs may comprise a stainless steel, or a shape memory/superelastic alloy such as a nitinol material. The basket legs 106 may have a rectangular cross section in those variations where the legs 106 are formed from ribbons, or the legs 106 may have a circular cross section in those
10 variations where the legs are formed from wires. As discussed below, the legs 106 may also have other cross section as desired. It is also contemplated that the legs 106 need not all have similar cross sections. For instance, the cross section of each of the legs 106 in a basket 104 may be individually chosen to optimize such factors as the resilience of the basket 104, or to optimize energy transfer characteristics. The legs
15 may also have a variable cross section along the length of the basket.

 Illustrated are variations of the inventive device 302 having a basket 104 comprising of four legs 106. It is preferred that the legs 106 are spaced at equal intervals around the expandable member or basket 104. For example, in variations of the invention having four legs 106, the legs 106 are preferably, but not necessarily
20 spaced at approximately 90 degree intervals around the basket 104. In variations having five legs 106, the legs 106 may be spaced at approximately 72 degree intervals. Other variations of the invention include devices having less than four legs or more than five legs. It is thought that the most effective number of legs is a compromise based on the size of the target airway, contact surface between the leg
25 106 and airway wall, and the maximum outer diameter of the elongated member 102.

 The proximal 108 and/or distal 110 joints may also contain adhesive to bind the legs 106. The basket legs 106 between the proximal 108 and distal joint 110 are formed into the basket shape 104 so that arch shaped portions of the basket legs 106

will contact the walls of an airway to facilitate energy transfer. Although the figures illustrate the basket legs 106 as having a semi-circular or arc shape the device is not limited to such shapes. For example, the legs 106 may have a more oblong shape or sharper bends to allow for a more parallel leg surface area that contacts the target tissue. Each leg 106 may have a center that is substantially parallel to the elongated body so that there is sufficient contact between the airway walls and the parallel portion of the leg 106. The center that is substantially parallel is usually referred to as the active region of the leg 106.

The length of the basket 104 between the proximal and distal 110 joints may be less than 35 mm when the basket 104 is in a first unexpanded state. The legs 106 may be coated with an insulating material (not shown) except at the tissue contact points. Alternatively, the legs 106 of the basket 104 may be exposed while the proximal 108 and distal joint 110 are insulated. In this variation, the basket 104 is formed of a resilient material which allows the distal end of the inventive device 302 to be confined by a sheath (not shown) for delivery of the device 302 to the treatment site and allows the basket 104 to return to its original basket shape upon deployment. In other words, a variation of the invention is that the basket self-expands from a first state to a second expanded state upon the removal of any constraining or restrictive member such as a sheath (not shown). The inventive device 302 is preferably configured such that the basket legs 106 have sufficient resilience to come into contact with the airway walls for treatment.

FIG. 5A further illustrates a variation of the inventive device 302 in which a distal end of the device 302 is provided with a distal tip 112 that can have a radius to facilitate insertion of the device 302 into the lungs and also to minimize the possibility of causing trauma to surrounding tissue. The tip 112 is preferably sized to prevent the gouging of airway by the sheath. The design of the distal tip is selected to be atraumatic. The size of the tip may be selected to be large enough to prevent the sheath from gouging airways yet small enough to pass in and out of a bronchoscope.

FIG. 5B illustrates a variation of the inventive device 302 having basket legs 108 connected to a distal end 114 of the elongated member 102 and forming a basket 104. In this variation, a proximal joint is found at the distal end 114 of the elongated member 102. The basket 104 is expanded radially, to its second state, during use to ensure contact between the energy transfer elements (not shown) and the airway walls (not shown) by, for example, pulling on a center pull wire 116 which is connected to a distal tip 118 of the expandable portion 104. The center pull wire 116 may extend through a lumen of the elongated member 102 towards a proximal portion (not shown) of the elongated member 102. It is also contemplated that the center pull wire 116 may be configured to deliver current to the energy transfer elements found on the expandable member 104. The inventive device 302 may be delivered to a treatment site through a delivery sheath 120 and may be drawn along or moved axially along the airway to treat the airway in a pattern of longitudinal or helical stripes.

As noted above, the basket 104 may be resilient or self-expanding (e.g., see FIG. 5A) to expand to a second expanded state or the basket 104 may require an expanding force (e.g., see FIG 5B). An example of this variation of the inventive device 304 is shown in FIG. 5B. In this variation, the basket 104 may be resilient and the sheath 120 may comprise the deployment member. In this variation, when the elongate body 102 and basket 104 are withdrawn into the sheath 120, the basket 104 contracts within the sheath 120 and assumes a first state. In one variation of the invention, upon advancing the basket 104 and elongate body 102 out of the sheath 120, the basket 104 may resiliently assume a second expanded state. In another variation of the invention, the basket 104 may assume a second expanded state with the aid of a wire 116. This wire may also be configured to deliver power to the energy exchange elements 106.

FIG. 5C illustrates another variation of the inventive device where an elongated member 102 of is configured to have a plurality of lumens 140 so that each of the basket legs 106 are isolated within the lumens 140 of the elongated member

102 until the legs 106 exit the elongated member 102 and connect at a proximal joint 108. The invention may have basket legs 106 selected with a sufficient length such that the ends of each of the legs 106 extend substantially into the lumens 140. As a result of being inserted deeply within the lumen, the ends of the legs 106 would
5 require significant travel before they exited the lumen 140. This feature provides added safety as it minimizes the risk of the basket legs 106 dislodging from the elongate member 102.

In another variation of the invention, the elongated member 102 may comprise concentric tubes (not shown) rather than multi-lumen tubes where basket
10 legs are inserted in the annulus between the tubes. It is also contemplated that an elongated member may be reinforced with the use of a reinforcing member. Such a reinforcing member may include a coiled wire or polymeric insert.

FIG. 5D-5I illustrate variations of the inventive device that use an expanding force to expand the basket. FIG. 5D illustrates a deployment member of the device.
15 FIG. 5E illustrates the device of FIG. 5D when the elongated member is moved in a distal direction to a deployment point. FIG. 5F-5G illustrates the elongated member 102, sheath 120, expandable member 104, distal tip 118, and wire 122 extending through the device. FIG. 5F illustrates the basket 104 in a first unexpanded state when the elongated member 102 and wire 122 are proximal of the deployment point
20 130. FIG. 5G illustrates the expansion of the basket 104 to a second expanded state as the elongated member 102 moves distally and the wire 122 is restrained at the deployment point 130.

Turning now to FIG. 5D, the deployment member may comprise a handle 124 which is adjacent to a proximal portion of an elongated member 102. The handle
25 may be designed to be operated by a single hand, either right or left. The handle may also have a control switch for operation of the device. Such a switch could control the power supply attached to the device as well. Also, the handle may be configured to determine the position of the device within a human body as the device is

advanced to a target site. For example, marks on the handle or even a readout could provide information to the user as to the relative deployment state of the expandable member. Also, a sensor may be placed on the handle 124, this sensor may be used to determine the position of the expandable member. Such a sensor could also be used to measure the size of the airway, such a measurement could be used as a control variable to determine the amount of energy that the device power supply must deliver. The handle 124 may control the expandable member using force compensation (e.g., a spring, etc.) or deflection limiting stops to control the expansion of the expandable member. Such force compensation or deflection stops provide a limit to the expansion member to avoid over-expansion of a particular airway.

Turning now to the handle 124 of FIG. 5D, an elongated member 102 may be slidably mounted to the handle. The variation of the invention depicted in these Figures may also, but does not necessarily, include a sheath 120 exterior to the elongated body 102. A wire 122 extends from the handle through the elongated member 102 and may be attached to a distal tip 118 of the device. The wire 122, elongated member 102, and distal tip (not shown) are slidably moveable in both a distal and proximal directions. The handle may also include a stop 126 which prevents the wire 122 from moving distally beyond a deployment point 130. The stop 126 may be connected to a spring (not shown) to limit the expansion of the expandable member upon reaching a pre-determined force. The handle 124 may include a control member 128 that is moveably attached to the handle 124 for moving the elongated member 102 in a distal/proximal direction. Although the handle 124 in the figures is depicted to have a control member 128 as illustrated, other variations of control members are also contemplated to be within the scope of this invention. For example, though not illustrated, a handle 124 may include other configurations, such as lever, thumb-wheel, screw-mechanism, ratchet mechanism, etc., which are attached to the handle 124 to provide control actuation for the expandable member.

FIG. 5E illustrates a variation of the inventive device when the elongated member 102 and wire 122 are moved in a distal direction. In this illustrations, a stop 126 prevents the wire 122 from moving distally of a deployment position 130. This illustration further illustrates a variation of the invention where the stop 126 is attached to springs 127 which provide force compensation for the expandable member on the device. Although not shown, a control member 128 may have a stop which limits its travel along a handle 124. Such a stop is an example of a deflection limiting mechanism which controls the movement of the control member 128, thus controlling the extent of the expansion of the expandable member.

FIG. 5F illustrates the invention when the expandable member or basket 104 is in a first unexpanded state. As noted above, the wire 122 is attached to a distal tip 118 of the device and both are prevented from distal movement when the wire 122 is in the deployment position 130. Therefore, as depicted in FIG. 5G, movement of the elongated member 102 in a distal direction against a distal tip 118, that is restrained by a wire 122, causes a basket 104 to compress between the advancing elongated member 102 and the stationary distal end 118. Thus, the basket 104 is forced outward and radially expands into a second expanded state. As noted above, the wire 122 may also be used to transfer energy to or from the energy transfer elements found on the basket 104. Also, it is contemplated that the wire 122 may be a wire, a ribbon, a tube, or of any other equivalent structure. Also contemplated, but not shown, is a detent means for maintaining the elongated member in a distal position to expand the basket 104 against the distal tip 118 without the need for continual applied force by a user of the device. Also contemplated is a ratchet member, or friction member to maintain the basket 104 in the expanded state.

FIG. 5H illustrates another variation of a deployment member. In this variation, a sheath 120 may be slidably attached to a handle 124. In this variation, the elongate member 102 is rigidly attached to the handle 124. The sheath 120 may be attached to a first control member 129. A wire 122 extends through the elongate

member 102 and is attached to the distal tip of the device (not shown). The wire 122 may be attached to a second control member 131. As indicated in FIG. 5I, proximal movement of the first control member 129 causes the sheath 120 to proximally retract over the elongate member 102 and uncover the expandable portion (not shown).

5 Proximal movement of the second control member 131 causes the wire 122, distal joint, and expandable member to move against the non-moving elongate member 102 which causes the expandable member to expand into a second state.

Turning now to the energy transfer elements located on the expandable portion, FIG. 5J-5L illustrate examples of energy transfer elements that may be
10 located on the expandable portion of the device. In the variation of the invention where the expandable portion comprises a basket having basket legs 106, the basket legs 106 may function as heat exchange elements. In other words, the device may be configured so that the leg is an electrode or the conductive heating element. In these variations, the leg 106 may be partially covered with an insulation only leaving an
15 active region exposed for delivery of energy to the airways. Examples of such insulation include a heat shrink sleeve, a dielectric polymeric coating, or other material which may function as an insulator.

FIG. 5J illustrates an example of a basket leg 106 with an energy transferring element 132 coiled around the leg 106. In this example, the energy transferring
20 element uses conductive heating and comprises a resistance heating element 132 coiled around the leg 106. FIG. 5K illustrates a variation of the invention having an RF electrode attached to the basket leg 106. The RF electrode may be attached to the basket leg 106 via the use of a fastener 134. For example, the electrode may be attached via the use of a heat shrink fastener 134, (e.g., polymeric material such as
25 PET or polyethylene tubing).

FIG. 5L illustrates another variation of the invention where the energy transfer element is a printed circuit 138 that is situated around the leg 106 and secured to the leg. Also contemplated, but not shown for use as energy transfer elements are a

polymeric heating material, an electrically conductive paint, a resistance element sputtered onto the leg in a pattern or formed on a substrate by photofabrication. Also, the basket leg itself may be chosen of appropriate size and resistivity to allow dual use as a basket and energy transfer element. Many nickel-chromium alloys have both high specific resistance and significant spring-like properties. In any variation of the invention the use of adhesives or other coatings may also be used to secure the energy transfer element to the basket leg 106. Also, the energy transfer elements are not limited to what is illustrated in the drawings. It is also contemplated that other types of energy transfer elements may be used such as radiant, laser, microwave, and heat energy.

FIG. 6A illustrates a variation of a distal tip 210 having a redundant joint. The distal tip 208 has a polymeric cap 210 covering the distal ends of the basket legs 106 and wire 212. The legs 106 are soldered 214 to the distal end of the wire 212. Also used to maintain the joint is an adhesive 216 substantially filling the polymeric cap 210. A multi-lumen piece 218 separates the legs 106 and wire 212. A side view of the multi-lumen piece 218 is shown in FIG. 6B. A multi-lumen tubing may be used for the multi-lumen piece 218. The ends 220 of the polymeric cap 210 may be heat formed or otherwise tapered down around the legs 106.

FIG. 6C illustrates another variation of a distal tip 222 having a redundant joint. The distal tip 222 has a polymeric cap 210 covering the distal ends of the basket legs 106 and wire 212. The legs 106 are soldered 214 to the distal end of the wire 212. Also used to maintain the joint is an adhesive 216 substantially filling the polymeric cap 210. A hypo-tube 224 covers the legs 106 and wire 212. A side view of the hypo-tube 224 is shown in FIG. 6D. The distal end of the hypo-tube 224 may be flared to seat a ball located on a distal end of the wire 212 and the legs 106. A proximal end of the hypo-tube 224 may be flared to provide greater interlock with ends 220 of the polymeric cap 210. As shown in FIG 6C, the ends of the legs 106 taper outwards from the hypo-tube 224 and form an area with a diameter larger than

the end of the cap 226 which may be tapered down around the legs 106 and wire 212. The ends 220 of the polymeric cap 210 may be heat formed or otherwise tapered down.

FIG. 6E shows another variation of the invention having a hoop or ring 228 at a proximal joint of the device. The hoop 228 may be soldered or welded to the legs 106 and keeps the legs 106 attached even if a joint fails between the legs and the elongate member 102. Also, the hoop 228 may electrically connect the legs, preventing disconnection of single leg 106 having a temperature sensing element attached.

The invention also includes a temperature detecting element (not shown). Examples of temperature detecting elements include thermocouples, infrared sensors, thermistors, resistance temperature detectors (RTDs), or any other apparatus capable of detecting temperatures or changes in temperature. The temperature detecting element is preferably placed in proximity to the expandable member. In the variation illustrated in FIG. 5C, a temperature sensor may be mounted along the pull wire 116. For the variations depicted in FIG. 5J-5L, a temperature sensor may be mounted between the energy transfer elements 132, 136, 138 and the leg 106. In one variation of the invention a temperature sensor is placed on a single basket leg 106 to provide a signal to control energy transfer. It is also contemplated that a temperature sensor may be placed on more than one basket leg 106, and/or on a central wire 116 to provide control for multiple areas of energy transfer. The temperature sensor may be placed on the inside of the basket leg 106 to protect the temperature sensor while still providing a position advantageous to determining the device temperature at the energy transfer element.

FIG. 5M illustrates a variation of the invention having thermocouple leads 139 attached to a leg 106 of the device. The leads may be soldered, welded, or otherwise attached to the leg 106. This variation of the invention shows both leads

139 of the thermocouple 137 attached in electrical communication to a leg 106 at separate joints 141. In this case, the temperature sensor is at the surface of the leg. This variation provides in case either joint becomes detached, the circuit will be open and the thermocouple 137 stops reading temperature. The device may also include both of the thermocouple leads as having the same joint.

FIG. 7A-7D illustrate variations of the device in which impedance may be varied by wiring the basket legs 106 in series or in parallel. FIG. 7A illustrates a series wiring diagram in which a current path 142 flows from a first leg to a second leg 106, a third leg 106, and a fourth leg 106 sequentially. FIG. 7B illustrates the series wiring diagram and shows a single wire 143 connecting the legs 106 in series. The wire 143 may, for example, extend to a distal end of the leg and wrap over itself to the proximal end of the leg 106. A covering (not shown) may be placed over the wire 143 wrapped leg 106 at the proximal end of the device. FIG. 7C illustrates another variation of a series wiring diagram. In this example, a wire 143 extends from the proximal end of a leg 106 to its distal end and then extends to the distal end of an adjacent leg 106 and extends back to the proximal end of the adjacent leg 106.

FIG. 7D illustrates a parallel wiring diagram in which a current path 142 flows to each leg 106. Series wiring has an added advantage in that all current will pass through each energy transfer element. By design, this configuration equalizes the heat dissipated at each leg through construction of legs with equal resistance. In addition, in the event of failure of any electrical connection, no energy is delivered. This provides an additional safety feature over parallel wiring. As mentioned elsewhere, the electrical current may be AC or DC. AC may be delivered in the RF range as a safety measure additional to electrical isolation. DC may be used to allow a portable device powered by a battery pack or provide an energy source within the device itself.

FIG. 8A-8C illustrates variation of the legs 106 of the basket 104. As discussed above, the legs may, for example, comprise a stainless steel, or a shape

memory/superelastic alloy such as a nitinol material. The basket legs 106 may have a rectangular cross section in those variations where the legs 106 are formed from ribbons, or the legs 106 may have a circular cross section in variations where the legs 106 are formed from wires. Also, a leg 106 may be configured to have a non-axisymmetric cross-section. For example, the leg may have an oval or flat cross section as well. The legs 106 of a basket 104 need not all have similar cross sections. For instance, the cross section of each of the legs 106 in a basket 104 may be individually chosen to optimize such factors as the resilience of the basket 104, or to optimize energy transfer characteristics. An example of a cross section of a basket leg 106 is seen in FIG. 8A which illustrates a top view of a basket leg 106 that has a contoured shape 144. In this illustration, the energy exchange element is not shown in the figure for clarity. One of the purposes of such a contoured shape 144 is illustrated in FIG. 8B. When the basket (not shown) expands to its second state, leg 106 is configured to bend at or substantially near to points 146. A benefit of such a configuration is to allow a substantially parallel active surface as defined by the contour shape 144. FIG. 8C illustrates another variation of a leg 106. In this variation, the leg 106 has a region of increased diameter 148 in the case of round wire, or increased width or thickness in the case of rectangular or other non-axisymmetric wire. Such a region 106 could also be a flat wire with bumps or protrusions creating areas of increased width of the flat wire. This region 148 may, for example, provide a stop that assists in locating insulation, heat shrink, or other external covering around the leg 106. Also contemplated is a leg 106 that consists of a composite construction. In this variation, the leg 106 may comprise of differing materials in predetermined regions to control the bending of the leg 106 as the basket 104 expands, or the leg may be constructed of different materials to selectively control regions of deliver of energy on the leg.

FIG. 9A-9D illustrates another variation of the inventive device in which the expandable member comprises basket from a single piece or sheet of material. Such

a configuration could comprise an etched, machined, laser cut, or otherwise manufactured piece of metal. FIG. 9A illustrates a partial view of a basket 104 formed from a single piece of material. The thickness of the material is, for example .005 inches but may vary as desired. The illustration of FIG. 9A shows the basket 104 prior to being wrapped about the Z direction as indicated. As shown, the legs 106 may be of varying length or they may be the same length 106 or a combination thereof. The basket 104 may have a distal portion 164 or basket head 164 which may be configured to facilitate construction of the device. For example, the basket head 164 may be notched 166 to obtain a desired shape as the basket is wrapped about the Z direction. FIG. 9B illustrates a variation of the basket head 165 being notched such that sections 165 of the material may be bent from the plane of the material to form tabs 165. Tabs 165 may be used to form mechanical joints with another part, such as a distal tip cap. FIG. 9C illustrates another variation of a basket 104 made from a single piece of material. In this example, the legs 106 of the basket 104 are bent in a direction orthogonal to the plane of the basket head 164. In this example, the distance between the ends of the legs 106 may be, for example, about 2.75 inches. FIG. 9D illustrates a variation of the proximal ends of the legs 106 of the basket 104. In this example, the proximal ends of the legs 106 may have features 168 which promote the structural integrity of the proximal joint (not shown) of the device. In this variation, the ends of the legs 106 have a saw-tooth design which improve the integrity of the proximal joint connecting the legs 106 to the elongated member. The variation of FIG. 9D also illustrates a proximal end of the leg 106 as having a radius, however, the end of the leg 106 may have other configurations as required. Also, the legs 106 may have a width of, for example, .012 inches and a separation of, for example, .016 inches. However, these dimensions may vary as needed.

FIG. 10 illustrates another variation of the inventive device 306 in which the expandable member comprises a balloon member 150. This variation of the device 306 includes electrodes 154 positioned on an exterior surface of the balloon member

150. The electrodes 154 may be connected to an energy source (not shown) by leads 156 extending through the balloon and through the lumen of an elongated member 102 . The balloon member 150 may be filled with a fluid 152 such as saline or air to bring the electrodes 154 into contact with the airway wall 10. As noted above, the electrodes may also be resistance heating elements, RF electrodes, or another suitable element for conducting energy transfer with the airway. Also, a single electrode may continuously surround a circumference of a balloon 150, or a plurality of electrodes may be spaced at certain intervals to substantially surround the circumference of a balloon 150.

FIG. 11 illustrates another variation of the inventive device 308 in which the expandable member comprises a balloon member 150 in which a fluid 152 within the balloon member 150 is heated by a heat generating element 158. The heat generating elements 158 are illustrated in the shape of coils surrounding the shaft of the elongated member 102, however other types of heat generating elements (not shown) shapes may also be used. The heat generating elements 154 may be used as resistance heaters by application of an electric current to the heat generating elements. Alternatively, radio frequency or microwave energy may be applied to the heat generating elements 158 to heat fluid 152 within the balloon member 150. The fluid may be configured to optimize conductive heat transfer from the electrodes 158 to the exterior of the balloon member 150. The heat then passes from an exterior of the balloon 150 to the airway wall 10. Radio frequency or microwave energy may also be applied indirectly to the airway wall through the fluid and the balloon. In addition, hot fluid may be transmitted to the balloon member 150 from an external heating device for conductive heating of the airway tissue.

Another variation of the inventive device 310 is illustrated in FIG. 12 includes a plurality of energy transfer elements 162 positioned on pre-shaped tines 160. The pre-shaped tines 160 may be outwardly biased such that they expand from a first shape inside sheath 120 into a second expanded shape once advanced out of sheath

120. The tines 160 may also be configured so that they retract into a first state once withdrawn into a sheath 120. The pre-shaped tines 160 may be connected to an elongate member 102 which is positioned within a sheath 120. The pre-shaped tines 160 and the energy transfer elements 162 may be delivered through a delivery sheath 120 to a treatment site within the airways. When the pre-shaped tines 160 exit a distal end of the sheath 120, the pre-shaped tines 160 may bend outward until the energy transfer elements 162 come into contact with the airway walls for transfer of energy with the airway walls.

FIG. 13 illustrates a variation of the inventive device 314 in which a elongated member 102 is provided with a plurality of energy transfer elements 170 positioned on at least one inflatable balloon 172. The energy transfer elements 170 may be RF electrodes or resistance heating elements. The balloons 172 are inflated through the elongated member 102 to cause the energy transfer elements 170 to come into contact with the airway walls 10. The energy transfer elements 170 are preferably connected to the energy source (not shown) by conductive wires (not shown) which extend from the energy transfer elements 170 through or along the balloons 172 and through the elongated member 102 to the energy source. In the variation where the energy transfer elements 170 are RF electrodes, the electrodes 170 may be used in a bipolar mode without an external electrode. Alternatively, the inventive device 314 may be operated in a monopolar mode with an external electrode (not shown, see FIG. 4). Another variation of the invention includes using resistance heating elements as the energy transfer elements 170. The energy transfer elements 170 may be a single continuous circular element or there may be a plurality of elements 170 spaced around the balloons 172.

An alternative of the inventive device 316 of FIG. 14 includes an elongated member 102 having one or more grooves 174 in an exterior surface. Positioned within the grooves 174 are electrodes 176 for delivery of energy to the airway walls. Although the grooves 174 have been illustrated in a longitudinal pattern, the grooves

may be easily configured in any desired pattern. Preferably, the inventive device 316 of FIG. 14 includes a biasing member (not shown) for biasing the elongated member 102 against an airway wall such that the electrodes 176 contact airway tissue. The biasing member (not shown) may be a spring element, an inflatable balloon element, or other biasing member. Alternatively, the biasing function may be performed by providing a preformed curve in the elongated member 102 which causes the device to curve into contact with the airway wall when extended from a delivery sheath (not shown).

FIG. 15 illustrates a variation of the inventive device 318 having one or more electrodes 178 connected to a distal end of an elongated tube 102. The electrodes 178 are supported between the distal end of the elongated tube 102 and a distal tip 180. A connecting shaft 182 supports the tip 180. Also connected between the distal end of the elongated member 102 and the distal tip 180 is a spring element 184 for biasing the electrodes 178 against a wall of the airway. The spring element 184 may have one end which slides in a track or groove in the elongated member 102 such that the spring 184 can flex to a variety of different positions depending on an internal diameter of the airway to be treated.

FIG. 16 illustrates an alternative of the inventive device 320 in which the one or more electrodes 186 are positioned on a body 188 secured to an end of an elongated member 102. In the FIG. 16 variation, the body 188 is illustrated as egg shaped, however, other body shapes may also be used. The electrodes 186 extend through holes 190 in the body 188 and along the body surface. A biasing member such as a spring element 184 is preferably provided on the body 188 for biasing the body with the electrodes 186 against the airway walls. Leads 192 are connected to the electrodes 186 and extend through the elongated member 102 to the energy source not shown.

FIGS. 17 and 18 illustrate embodiments of the invention 322, 324 in which electrodes 194 in the form of wires are positioned in one or more lumens 196 of an

elongated member 102. Openings 198 are formed in side walls of the elongated member 102 to expose the electrodes 194 to the surrounding tissue. As shown in FIG. 17, the inventive device 322 may have multiple lumens 196 with electrodes 194 provided in each of the lumens 196. The side wall of the inventive device 322 is cut away to expose one or more of the electrodes 194 through a side wall opening 198. In FIG. 17, the opening 198 exposes two electrodes 194 positioned in adjacent lumens. The inventive device 322 may be provided with a biasing member as discussed above to bring the electrodes 195 of the device into contact with the airway wall.

Another variation of the inventive device 324 as shown in FIG. 18 includes an elongated member 102 which has an expandable loop shaped member 202 to allow the electrodes 194 to be exposed on opposite sides of the device 324 which contacts opposite sides of the airway. The resilience of the loop shaped member 202 causes the electrodes 194 to come into contact with the airway walls.

FIGS. 19 and 20 illustrate a further variation of the inventive device 326 having an expandable member 204 in a first non-expanded state and in a second expanded state. FIG. 19 illustrates the device as having one or more loop shaped electrodes 204 connected to an elongated member 102. In the unexpanded position shown in FIG. 19, the loop of the electrode 204 lies along the sides of a central core 206. A distal tip of the loop electrode 204 is secured to the core 206 and to a distal tip 208. The core 206 may be slidable in a lumen of the elongated member 102. Once the inventive device 326 has been positioned with the distal end in the airway to be treated, the electrode 204 is expanded by pulling the core 206 proximally with respect to the elongated member 102, as shown in FIG. 20. Alternatively, the electrode 204 or the core 206 may be spring biased to return to a configuration of FIG. 20 when a constraining force is removed. This constraining force may be applied by a delivery sheath or bronchoscope through which the inventive device 326 is inserted or by a releasable catch.

5 The treatment of the tissue in the airway walls by transfer of energy according to the present invention provides improved long term relief from asthma symptoms for some asthma sufferers. However, over time, some amount of smooth muscle or mucus gland cells which were not affected by an initial treatment may regenerate and treatment may have to be repeated after a period of time such as one or more months or years.

10 The airways which are treated with the device according to the present invention are preferably 1 mm in diameter or greater, more preferably 3 mm in diameter. The devices are preferably used to treat airways of the second to eighth generation, more preferably airways of the second to sixth generation.

15 Although the present invention has been described in detail with respect to devices for the treatment of airways in the lungs, it should be understood that the present invention may also be used for treatment of other body conduits. For example, the treatment system may be used for reducing smooth muscle and spasms of the esophagus of patients with achalasia or esophageal spasm, in coronary arteries of patients with Prinzmetal's angina variant, for ureteral spasm, for urethral spasm, and irritable bowel disorders.

20 The devices and method describe herein provide a more effective and/or permanent treatment for asthma than the currently used bronchodilating drugs, drugs for reducing mucus secretion, and drugs for decreasing inflammation.

25 Moreover, the inventive device may also include a steering member configured to guide the device to a desired target location. For example, this steering member may deflect a distal tip of the device in a desired direction to navigate to a desired bronchi or bronchiole. Also contemplated is the use of the device with a vision system. Such a vision system may comprise a fiber optic cable which allows a user of the device to guide a distal tip of the device to its desired location. The vision system may include a CCD chip.

Also contemplated as the inventive device is the use of a power supply for providing energy as described above. The power supply provides the energy to be delivered to airway tissue via the energy transfer device. While the main goal of the power supply is to deliver enough energy to produce the desired effect, the power supply must also deliver the energy for a sufficient duration such that the effect persists. This is accomplished by a time setting which may be entered into the power supply memory by a user.

A power supply may also include circuitry for monitoring parameters of energy transfer: (for example, voltage, current, power, impedance, as well as temperature from the temperature sensing element), and use this information to control the amount of energy delivered.

A power supply may also include control modes for delivering energy safely and effectively. Energy may be delivered in open loop power control mode for a specific time duration. Energy may also be delivered in temperature control mode, with output power varied to maintain a certain temperature for a specific time duration. In the case of RF energy delivery via RF electrodes, the power supply may operate in impedance control mode.

In temperature control mode with RF electrodes described here, the power supply will operate at up to a 75°C setting. The duration must be long enough to produce the desired effect, but as short as possible to allow treatment of all of the desired target airways within a lung. For example, 5 to 10 seconds per activation (while the device is stationary) is preferred. Shorter duration with higher temperature will also produce acceptable acute effect.

Using RF electrodes as described above in power control mode, power ranges of 10-15W with durations of 3-5 seconds are preferred but may be varied. It should be noted that different device constructions utilize different parameter settings to achieve the desired effect. For example, while direct RF electrodes typically utilize temperatures up to 75°C in temperature control mode, the resistively heated

electrodes may utilize temperatures up to 90°C. Also, in addition to the control nodes specified above, the power supply may include control algorithms to limit excessive thermal damage to the airway tissue. For example, in order to stop delivery of energy in the event of contact between airway tissue and device legs having temperature sensing capabilities, an algorithm may be employed to shut down energy delivery if the sensed temperature does not rise by a certain number of degrees in a pre-specified amount of time after energy delivery begins. Another way to stop energy delivery includes shutting down a power supply if the temperature ramp is not within a predefined range at any time during energy delivery. Other algorithms include shutting down a power supply if a maximum temperature setting is exceeded or shutting down a power supply if the sensed temperature suddenly changes, such a change includes either a drop or rise, this change may indicate failure of the temperature sensing element.

Moreover, a variation of the invention includes configuring each energy exchange element independently to provide selective energy transfer radially about the device. As discussed above, another variation of the invention includes providing feedback control to determine the impedance of the airway to determine the power required by a power supply. Again, as discussed above, the feedback control could also be used to determine the size of the airway in which the device is positioned.

Further details as to the use or other variation of the apparatus described herein may be drawn from the background which is intended to form part of the present invention. It is noted that this invention has been described and specific examples of the invention have been portrayed to convey a proper understanding of the invention. The use of such examples is not intended to limit the invention in any way. Additionally, to the extent that there are variations of the invention which are within the spirit of the disclosure and are equivalent to features found in the claims, it is the intent that the claims cover those variations as well. All equivalents are considered to be within the scope of the claimed invention, even those which may not

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